

## **REMARKS AND RESPONSE**

### **A. Status of the Claims**

Claim 1 has been amended herein and no claims have been canceled. Thus, claims 1-16 are currently pending in the case.

### **B. Rejections Under 35 U.S.C. § 102(b)**

The Action alleges that claim 1 is anticipated by Fry *et al.* (U.S. Patent 5,631,152), however the Action has failed to make a *prima facie* case for anticipation. In order to anticipate a claim a single reference must expressly or inherently disclose *all* of the claim elements and a proper rejection must specifically identify each claim element in the reference, see *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988). The instant Action fails to identify where Fry explicitly or implicitly teaches all of the elements of claim 1. For example, the Action fails to indicate where Fry teaches the use of a multiple bud-inducing media in a method for making transgenic wheat. Thus, no *prima facie* case for anticipation has been set forth. In view of the foregoing, it is respectfully requested that this rejection be removed.

### **C. Rejections Under 35 U.S.C. § 103**

The Action has rejected claims 2-16 as obvious over Zhou *et al.* (1995) in view of Tegeder *et al.* (1995), further in view of Weeks *et al.* (1993) and still further in view of Cheng *et al.* (1997). However, the Action has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art references, when combined, must teach or suggest all the claim limitations. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success in the combination. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The Action has failed to satisfy all three requirements for establishment of obviousness under 35 U.S.C. § 103.

For example, the Action has failed to clearly identify how the cited combination of references teach all elements of the instant claims. As outlined above, the Action has failed to identify any reference that teaches the use of a multiple bud inducing media in a method for transforming wheat. In fact, the Action fails to identify any reference that teaches or suggests the use of a multiple bud-inducing media. Thus, no *prima facie* case of obviousness has been set forth in the Action.

Even if the cited references did disclose all of the elements of the instant claims, which they do not, the Action has still failed to identify any motivation or suggestion to combine the references to achieve the method of the instant invention. The only motivation to combine the references provided by the Action is that “Weeks *et al* teach that wheat is the largest crop in the world in terms of production and that monocotyledonous plants, cereals in particular, have lagged behind dicotyledonous plants in ease and efficiency of transformation,” (page 7 of the Action dated November 22, 2005). However, Applicants fail to see how this provides any specific motivation to combine, for example, the wheat transformation methods of Zhou with the cytokinin media of Tegeder. Furthermore, Applicants note that, while Zhou concerns methods for transforming wheat, Tegeder concerns methods for regenerating an unrelated plant, *Vicia faba* (horsebean). Thus, Applicants note that these references constitute non-analogous prior art and are not properly combinable. Hence, the Action fails to provide any motivation to combine the cited references to produce the claimed method for transforming wheat.

There would also be no reasonable expectation of success in the combination of references cited by the Action. For example, there would be no expectation of success in applying the teaching of Tegeder regarding *Vicia faba* to methods for transforming wheat (*e.g.*, from Zhou), since these plants are unrelated and may respond differently to cytokinins, particularly given that one is a monocot and the other a dicot. Furthermore, there is no suggestion that any combination of the cited references could be used to generate multiple transgenic wheat explants by inducing multiple bud formation. Thus, the combination of the methods and media of Zhou with the cytokinin media of Tegeder in a wheat transformation method employing a multiple bud-inducing media would be completely unpredictable. There must be at least some degree of predictability for there to be a reasonable expectation of success (MPEP §2143.03, *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)). Hence, since the use of the multiple bud-inducing media in methods of the invention (*e.g.*, using a media a

cytokinin and an auxin) is unpredictable there could be no reasonable expectation of success in, for example, the combination of Zhou and Tegeder.

Furthermore, even if a *prima facie* case were set forth, which the Action has not done, none of the references of record teach or suggest the surprising and unexpected results obtained with the methods of the instant invention. For example, “[a] greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness” *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). Such a greater than expected result is realized using the methods of the invention. In particular, the instant invention provides a methods for producing *multiple* transgenic plants from a single explant by virtue of a multiple bud-inducing media. Such results would not have been expected and could not have been predicted in view of the prior art of record. As shown in Table 3 of the specification (Page 19) the multiple bud inducing media of the invention is able to producing 20-80 buds from a single primary meristem in over 70% of wheat explants whereas none of the explants grown in a control medium (TDZ alone) produced such numbers. Thus, the methods of the invention provide for the production of a multitude of transgenic plants from a single explant. These results not only constitute a quantitative difference over the art of record (*i.e.*, in providing a method for producing a large number of transgenic plants) but also a difference in *kind* in that they enable production of multiple transgenic plants from a single starting explant. Thus, methods of the instant invention offer surprising an unexpected advantages relative the prior art. Hence, even if a *prima facie* case for obviousness was set forth, which has not been done, it would still not render obvious the instant claims in view the surprising and unexpected results achieved by the new methods.

Withdrawal of the rejection is thus respectfully requested.

**D. Previous Rejections Under 35 U.S.C. § 112, First Paragraph (Enablement)**

The Action previously rejected claims 1-16 as lacking enablement vis-à-vis the use of *Agrobacterium*-transformation in the methods of the invention. The Action’s argument seems to be that in view of the teachings of Kless *et al.* (1992), *Agrobacterium*-transformation may be as effective as biolistic transformation and/or may require different parameters for optimization. Furthermore, the Action indicated that the application fails to teach that there are drawbacks to using *Agrobacterium*-mediated transformation in wheat as taught by Sahrawat *et al.* However, Applicants note that these arguments are irrelevant to the issue of enablement since each of the

references cited by the Action demonstrates that methods for transforming wheat via *Agrobacterium* were known in the art at the time the invention was made. For example, the Action has cited Cheng *et al.* (1997) and, as stated on the record by the Examiner, Cheng teaches effective methods for *Agrobacterium*-mediated transformation of wheat (Page 972, first column, second paragraph to second column, end of second paragraph). Thus, methods for transforming wheat using *Agrobacterium* were known in the art at the time the instant invention was made. The Action has failed to provide any evidence that *Agrobacterium*-transformation would be inoperative when used in the context of the methods of the invention. The mere assertion that *Agrobacterium*-mediated transformation is “problematic” in wheat is insufficient to support the rejection since, as stated in *In re Cook and Merigold*, 439 F2d 730, 169 U.S.P.Q. 298 (C.C.P.A. 1971), a claim may omit “factors which must be presumed to be within the level of ordinary skill in the art.” Clearly, the optimization of *Agrobacterium*-transformation of wheat to which the Action refers would have been well within the level of skill in the art in view of the references of record (*e.g.*, Cheng *et al.*). Thus, in view of the forgoing arguments Applicants assert that the rejection of the claims under 35 U.S.C. §112, first paragraph is rendered moot.

**E. Obviousness Type Double Patenting**

The Action has failed to set forth a *prima facie* case for obviousness type double patenting regarding claim 1. The instant rejection merely states that claim 1 is “not patentability distinct” from claims 1 and 7 of Fry *et al.* (U.S. Patent 5,631,152). However, the Action fails to set forth a case for obviousness of the instant claims over Fry in combination with any of the other references of record in the case. Specifically, Applicants fully demonstrate herein above that Fry *et al.* fails to teach or suggest all elements of the claims alone or in combination with the remaining cited art. The rejection is therefore now believed to be moot and withdrawal thereof is thus respectfully requested.

**F. Conclusions**

In view of the foregoing amendments and arguments, Applicants assert that the instant application is in condition for allowance and such favorable action is requested. Should the Examiner have any questions regarding these amendments he is invited to contact the undersigned attorney at (512) 536-3085.

Respectfully submitted,



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